K091702

510(k) Summary

AUG 0 7 2009

Submitter:

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Date Prepared: May 20, 2009

Name of Device: CDB Flip-Slide-Clip Bracket

Classification Name: Bracket, Ceramic, Orthodontic

Device Classification:
Regulatory class II
Product code: NJM
Classification Panel: Dental
Regulation Number: 872.5470

Predicate Devices(s):

Company	Product	510(k)
CDB Corporation	CDB Clip	K080906
CDB Corporation	Reflection Ceramic Dental Bracket	K922499
Dentsply Int.	In-Ovation C	K060837

Device Description: CDB Flip-Slide-Clip Brackets are bonded to teeth to apply pressure to the tooth, transmitted through a flexible orthodontic wire, to alter the tooth position. The modified orthodontic ceramic bracket has both aesthetic and self-ligating qualities. The modifications were aimed at facilitating easier orthodontic wire ligation

Indications: The CDB Flip-Slide-Clip Bracket is indicated for orthodontic movement of natural teeth.

Technical Characteristics: The function and performance of the CDB Flip-Slide-Clip Bracket is similar to the predicate. Minor design changes and incorporation of self-ligation are the only modifications made to the Orthodontic Ceramic Brackets (Reflection®) (K922499).

There are no changes in the intended use and fundamental scientific technology. All of the materials used in the device have been used in legally marketed CDB Corporation's devices. We believe that the modified device is substantially equivalent to the predicate Orthodontic Ceramic Brackets (In-Ovation C®) (K060837).

Conclusion:

By definition, a device is substantially equivalent when the device has the same intended use and the same technological characteristics as the predicate device.

There are no major differences between the CDB Flip-Slide-Clip Bracket and the predicate device(s) cited, therefore the CDB Flip-Slide-Clip Bracket does not raise any questions regarding the safety and effectiveness.

The CDB Flip-Slide-Clip Bracket, as designed, is as safe and effective as the predicate device(s) and the device is determined to be substantially equivalent to the referenced predicate device(s) currently on the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

AUG 0 7 2009

Mr. Charles Vernon
Quality/Regulatory Affairs Manager
CDB Corporation
9201 Industrial Boulevard
Leland, North Carolina 28451

Re: K091702
Trade/Device Name: CDB Flip-Slide-Clip Self Ligating Bracket
Regulation Number: 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: II
Product Code: NJM
Dated: May 28, 2009
Received: June 10, 2009

Dear Mr. Vernon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091702

Device Name: CDB Flip-Slide-Clip Self Ligating Bracket

Indications for Use:

The CDB Flip-Slide-Clip Bracket is indicated for orthodontic movement of natural teeth.

Prescription Use ___☑____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K091702